

---

## **THE STUDY OF SCOPE AND IMPLEMENTATION OF LEAN ASPECTS IN PHARMACEUTICAL INDUSTRY**

**<sup>1</sup>V. Jaiganesh, <sup>2</sup>Dr. J. Clement Sudhahar**

<sup>1</sup>Part-time PhD Management Sciences, Karunya University.

<sup>2</sup>Professor Management Sciences, Karunya University

### **ABSTRACT**

Today most of the pharmaceutical companies particularly the small molecule domain, faces unprecedented challenges of escalating costs, delivering the quality products and innovations within the short term period with increasing competitive pressure from other companies. In other industries, process improvement approaches such as Lean, Six Sigma etc., have delivered the benefits in speed, quality and cost of delivery. In this paper, specific attention is given to the three key points from management point of view is that Very high productivity, Very short lead times and Exceptional product quality for any drug product. Currently, pharmaceutical industry has been slow to adopt the lean manufacturing unlike many sectors where it has been successfully deployed. In fact, Lean and cGMP go hand in hand as quality is sustained at a higher level with lower costs due to lean principles that are applied. This research study attempts to sketch out the scope and implementation ways to implement lean management principles existing in the pharmaceutical manufacturing and thereby improve the quality of products and services. This study adds to the literature by providing background information regarding the current status of lean involvement in quality system in the pharmaceutical manufacturing sectors.

**Keywords:** Very high productivity, Short lead times, Lean, Product Quality, Cost of delivery

### **1. INTRODUCTION**

In olden days, Lean strategies have been developed to eliminate or reduce waste and thus improve operational efficiency in a manufacturing environment. However, in practice manufacturers encounter difficulties to select appropriate lean strategies within their resource constraints and to quantitatively evaluate the perceived value of manufacturing waste reduction.

In case of pharmaceutical sector, many pharmaceutical organizations had shown a willingness to simplify operations, processes and reduce costs via lean implementation. Nowadays, Pharma industries are under tremendous pressure to improve its competitive business: R&D

methods, manufacturing efficiency and whole supply chain performance. These organizations are struggling to find ways to cut costs.

In any industry where success is increasingly driven by satisfaction scorecards, reliable access to key talent is essential for meeting the demand for quality service. Over the last decade lean implementation has become the vital driver of operational change, eliminating waste and improving process. It is important to note that lean is heavily based on the mindset of the people and practices that continuous improvement can be found through the power of respect for people. The culture of the company is crucial in designing the business system that motivates people to want to improve, teaching them the tools, methods and principles and motivates them to apply those tools every day.

Lean scope and implementation improves the manufacturing process and business strategy and it involves the employees at all levels.

Today Industry trends shows that many pharmaceutical manufacturers are following some of the manufacturing principles in the way for significant improvement of operational efficiency and quality, while facilitating compliance. To ensure a solid position on the market and competitive advantage they are looking to increase the efficiency of their operational and manufacturing process - optimizing resources, improving efficiency and short lead times with best product quality.

Even if the change is good and beneficial, its lack of acceptance by the relevant stakeholders can bring in the uncertainty in the consequence of the change. Nowadays, Pharma industry faces the dilemma between pursuing the competitive advantage of cutting edge technology and the risk of uncertainty associated with it. So, the Implementing lean is a journey, not a process

## **2. OBJECTIVES / IMPORTANCE OF THE STUDY**

This research study involves in the “**Scope and Implementation of Lean aspects in Pharmaceutical Industry**”. This research study is to find out the scope and implementation of lean principles in the Pharma environment which in turn not identified and not applied as an effective tool in the business processes.

The following core objectives were taken into consideration during the research study,

- Is there any scope for lean applications?
- Proper selection of the lean methods for the implementation?
- People involvement and company culture?
- View about organizational structure and quality system followed in the selected pharmaceutical companies in Hyderabad, Andhra Pradesh.
- Factors influencing quality system management in medium scale pharmaceutical firms.
- Steps implemented to improve the quality / productivity to larger extent in the surveyed pharmaceutical firms.
- How the whole system functions towards the Very high product quality with respect to cost and productivity?
- Identify the factors which determine the complete quality system management of the selected pharmaceutical firms. (Quality Focus)
- What are the management principles / factors already exist with the pharmaceutical industries but the implementation aspects are very weak. (Tools / Goals)
- Whether lean management principles can be applied effectively?
- What is the business process and workflow?

- To offer suitable suggestions for implementation of lean, improvement, conclusions in the implementation of the lean management principles in the pharmaceutical firms to enhance the high productivity, short lead times thus by reduce the cost.

*Note: All the above factors are covered in the survey questionnaire.*

## **2.1. UNDERSTANDING THE SCOPE OF LEAN**

### **2.1.1 STATEMENT OF THE PROBLEM**

Lean has entered management consciousness in a big way in recent years. Nowadays many pharmaceutical companies are relying on the management concepts to improve the business processes. However, in most cases companies took only few steps towards the identifying and implementation of lean principles before but on later stage they are falling back into old habits. As a result, the Pharmaceutical industries lag in efficiency behind other major manufacturing industries such as the automotive and consumer goods sectors.

Actually 20 years ago, many manufacturers from other industries learned how to make significant, sustainable improvements to their profitability by taking a holistic look at their overall cost structure.

Pharmaceutical firms mainly focused on the high productivity, short lead times, required quality and compliance standard of pharmaceutical manufacturing are often cited as limiting factors in creating greater efficiency and many companies do better. Although the pharmaceutical industry tends to view itself as unique-which in some ways it is – pharmaceutical companies can learn several lessons from the companies that made the difficult but essential transformation to lean manufacturing.

Pharma companies started from the false assumption that implementing lean principles and processes would automatically lead to a reduction in overstaffing. In fact, lean processes only address the lack of process optimization. In fact lean processes require leadership from the top level of the company and at each subsequent level. Many companies initially believed that becoming a lean manufacturer would take about two years. However, they discovered that lean manufacturing is such a different method of operation that achieving full implementation takes four to five years but lean is not just an activity it is a process.

Identifying the lean and bringing about the implementation in Pharma is easier said than done. For any implementation – people, technology and processes that form the backbone of business are receptive to the inherent change. In particular, the Pharma industries may limit the degree to which this industry can adopt lean supply practices. Mostly, regulatory authorities do not necessarily share the view that lean manufacturing and GMP standards as comparable.

First step towards the lean is to understand and accept the need for change. Despite its focus on quality, it is the fact that pharmaceutical industry has failed to keep up with other industries in terms of manufacturing efficiency and productivity, the main reason for this being high costs and burden involved in revalidating any process change, even though changes were made in the spirit of improvement.

In the past, pharmaceutical industry for which the principles of good manufacturing practice are mandatory, has slowly been embracing lean manufacturing, in contrast to other sectors that adopted it relatively quickly and successfully.

Therefore, this study emphasis on the finding out the scope and implementation of lean principles in the pharmaceutical industry and thereby improve the productivity and operational efficiency.

## 2.2 HYPOTHESIS OF THE STUDY:

Lean's dual objectives, to reduce or eliminate waste and to create value, differ from cGMP objective which is to ensure that controls are in place to deliver a safe and effective medicinal product with good quality. In most cases, cGMP and lean management principles do overlap in the pharmaceutical manufacturing environment. So, effective lean management principles to be identified in the Pharma environment and utilised to improve the operational efficiency.

Industries are concern about the product quality with respect to cost and productivity. While considering important research issues, it was found that there is a definite role for management in quality control and quality assurance in implementing lean principles. Only if quality control and quality assurance are strictly adopted, the management goals such as name of the company, sales and profits could be achieved since due to effective quality systems the company would be producing quality products.

At present, it is found that there is a lack of coordination between management function and proper quality enforcement. In order to meet the strict quality requirements, management function and quality enforcement have to be coordinated, have to move in tandem but not to be separated.

Scope and Implementation of Lean aspects in cGMP environment:

- 1) Existing quality system to be compared with Lean principles with respect to the optimization of the processes and improve high productivity
- 2) Implementation of the Identified management principles to enhance short lead time and improve product quality.

Sometimes it takes decades to implement 100% of the identified management principles. Quality management system does not depend upon the capital investment and percentage of operating expenditure on quality control / quality assurance.

As more and more of the lean implementation in the health care business is preceded this way, the concept of a technology implementation to the customer and acceptance of the system will be difficult but it takes long pathway to accept in the society.

## 2.3. RESEARCH METHODOLOGY:

- **STUDY AREA**
- **SAMPLING PROCEDURE & DATA COLLECTION**
- **FRAME WORK OF ANALYSIS**
- **DATA ANALYSIS & INTERPRETATION**

Research is a careful investigation or enquiry especially through search for new facts in any branch of knowledge. Descriptive research has been used which involves surveys and fact findings.

2.3.1 Study Area: The study area refers only Hyderabad city, Andhra Pradesh.

2.3.2 Sampling Procedure & Data collection: The data were collected through different sampling technique (refers to different ways of sampling approach) and Primary data through an interview schedule was used as a tool for collecting the data.

2.3.3 Frame work of Analysis: Percentage Analysis.

2.3.4 Data Analysis and Interpretation.

**Sampling Procedure:** *Sampling was carried out in Hyderabad city, Andhra Pradesh, INDIA. The data was collected through various sources like Management Guides Websites (response through internet) and Friends & Relatives, direct interviews.*

During study, the data was collected as a whole and then segregated into various parts. Then, the collected data was organized and reviewed. Relevant data were taken into consideration and few data was kept for the reference purpose. Questionnaire with personnel interview conversation was done much relevant to the study. The collected data was considered and tabulated in the final stage of the

report. Further, Histogram graphical representation was made to interpret the results from the collected data.

The current study reveals that the scope and lean implementation aspects along with awareness within the employees were studied and represented below,

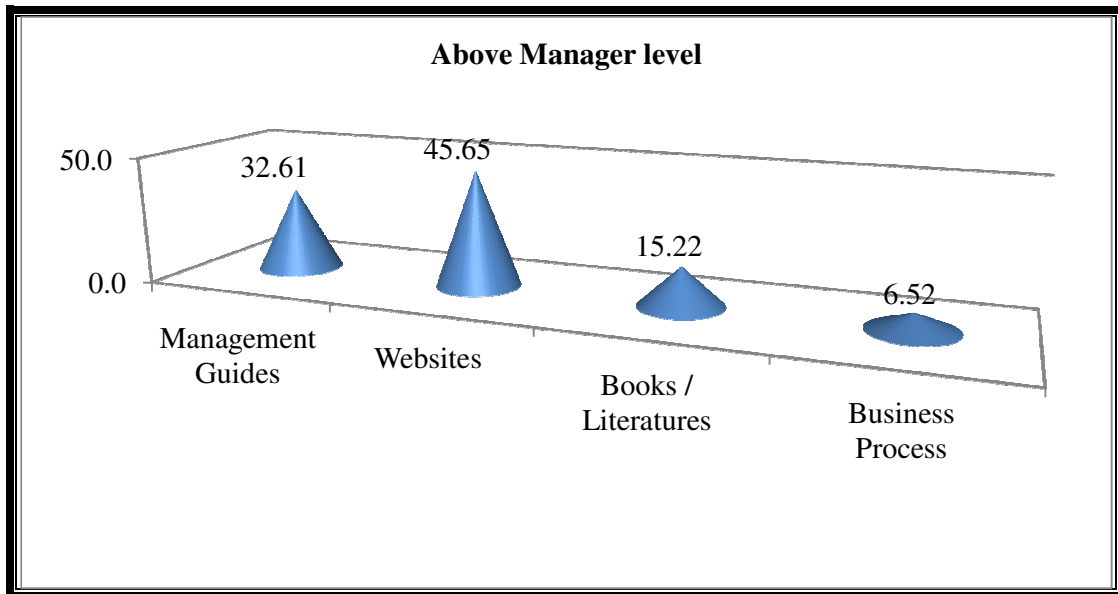
**Table1. Available Scope of the LEAN aspects in Pharma industry:**

*(Lean aspects are Very high productivity, Short Lead Time, Product Quality value etc)*

Sources of Awareness	Above Manager level		Below Manager level	
	No: of respondents	Percentage (%)	No: of respondents	Percentage (%)
Management guides	15	32.61	45	48.91
Websites	21	45.65	29	31.52
Books / Literatures	07	15.22	13	14.13
Business Process	03	6.52	05	5.43

Source: Primary data

Histogram representation: Figures Table1. Scope of LEAN aspects in Pharma industry. (Y axis refers the % awareness)



**Figure 1: Above Manager Level**

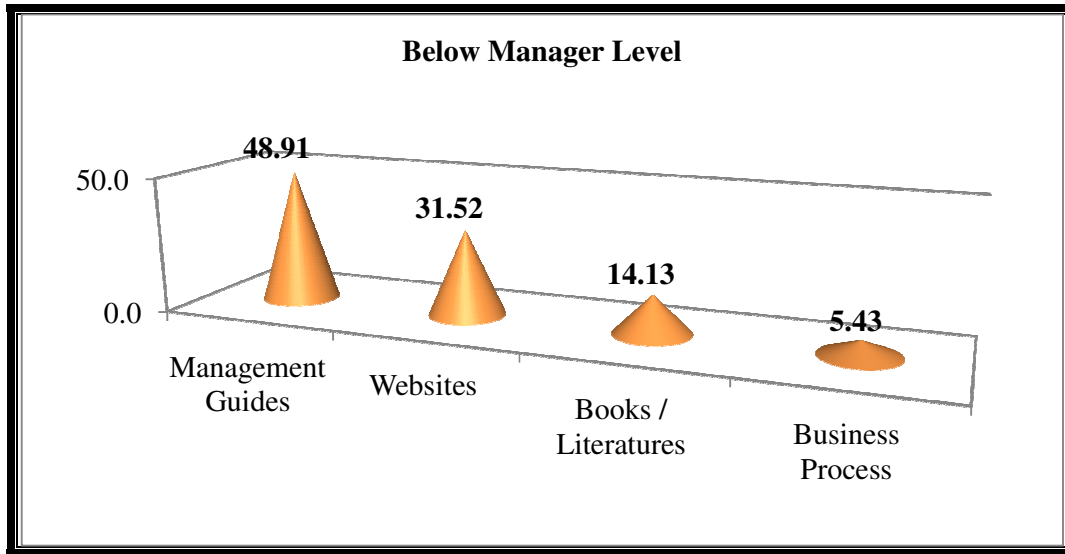


Figure 2: Below Manager Level

#### Inferences:

From the above data represented in the Figure 1, **Above manager level** data shows that (45.65%) of the respondents became aware through website and (32.61%) of the respondents through some of the management guidelines. Other awareness areas like books and literature (15.22%) and Business processes shows (6.52%) with reducing trend. If we look into the area of business process, this shows the less percentage of (6.20%) from the respondents.

**Below manager level** Figure 2 shows that data shows that (31.52%) of the respondents became aware through website and (48.91%) of the respondents through some of the management guidelines. Other awareness areas like books and literature (14.13%) and Business processes shows (5.43%) with reducing trend.

If we look into the area of business process, this shows the less percentage of (5.43%) from the respondents. So, in current scenario of the competitive world, the pharmaceutical firms were not concentrating in the implementation of the lean management principles and methods. Hence, the implementation of the lean management principles is not the part of the business process.

The above data clearly indicates that the pharmaceutical firms are growing in the Industrial sector in many ways but they are not concentrating in the implementation of the lean aspects and management tools and aspects.

Based on the data, pharmaceutical firms should look into the scope of the management aspect to implement the lean management principles to enhance the operational excellence with more productivity.

### 3. RESEARCH STUDY / SURVEY – THROUGH QUESTIONNAIRE / DIRECT INTERVIEW

About 6 pharmaceutical Industries were surveyed through Questionnaire / Direct interview with the senior / middle level peoples in Hyderabad city, Andhra Pradesh to understand the Scope and Implementation of lean management principles in the Pharma manufacturing environment. The following management aspects are identified which in turn improves the product quality. The major aspects which are identified in cGMP environment as well as LEAN management principles are

Very High Productivity, Robust Design, Manufacturing Capability, Validated process, Lead time, Product Quality and Implementation of LEAN tools etc.  
The above factors will immensely contribute to the Pharma industry in many ways for the operational excellence with balanced productivity and Quality.

**3.1 METHOD OF SURVEY:**

To understand current scenario in the Pharma industry, the survey questionnaire was prepared as per the research study requirement. Then, the selected Pharma firms were identified and visited. The survey questionnaire was distributed to the middle level management peoples and taken back with the comments. Further, the direct interview was performed at each senior level and information was collected and scrutinized as per the study requirement.

This study includes many stages:

- (a) Defining the Lean Practices based on criteria such as the inclusion of practices that workers could observe, interact with and use on a daily basis;
- (b) Defining the attributes for each practice, emphasizing the dimensions which were typical of their implementation in Lean Practices in cGMP environments;
- (c) Defining a set of evidence and sources of evidence for assessing the existence of each lean attribute – the sources of evidence included direct observations, analysis of documents, interviews and a feedback meeting to validate the assessment results with company representatives.

This study supports the identification of improvement opportunities in cGMP performance based on the analysis of their interfaces.

Some peoples were not properly effectively during the course interview but few suggestions were taken as a part of research study.

Overall the responses / informations / suggestions received from the Pharma companies were found to be adequate for the research study and tabulated in Table 2.

To identify the SCOPE and IMPLEMENTATION of LEAN ASPECTS in the PHARMA INDUSTRY, the following survey and review was conducted in the various pharmaceutical firms and outcomes are tabulated below,

**Table 2 SURVEY RELATED to LEAN concepts and aspects in the Pharma manufacturing:**

Survey Questionnaire Focussed on the below aspects related to LEAN	COMPANIES SURVEYED FOR THE STUDY*					
	A	B	C	D	E	F
% Acceptance of LEAN implementation	75	50	75	50	75	25
% Robust Design & Process	25	50	50	50	25	50
% Manufacturing capability	75	50	75	50	75	75
% Very High Productivity	75	50	75	50	75	50
% Short Lead Time	25	25	25	50	25	50
% Validated process	25	50	25	50	25	50
% Product Quality	75	50	75	50	75	75
% Current level of Implementation of LEAN	25	25	25	25	50	25

*Note:*

- \* ABCDEF refers to the various Pharmaceutical companies surveyed around Hyderabad city, Andhra Pradesh.
- % refers to the Average data: Scale used in the Survey Questionnaire relates to the current quality system ,  
Very Less – 25%, Moderate – 50%, Good – 75% Excellent – 100%

*Source: Primary data, % calculated from 100%, hence data collected for comparison only.*

Note: The research survey (questionnaire / discussion) was conducted in the pharmaceutical companies with the Quality related peoples / teams (senior / middle level) in the various departments. Direct interview / discussion are conducted with questionnaire (above aspects) with 6 out of selected 11 medium and largest pharmaceutical firms. (*Name of the surveyed organization names not mentioned, but supporting questionnaire data is available*). *Source: Primary data, % calculated from survey.*

**Information about the surveyed companies in Hyderabad:**

A) XXXX Pharma limited:

- \* Formulation Unit
- \* Manufacture of the solid oral dosage forms e.g. Tablets
- \* Facility approved by USFDA, ISO 9001:2008 standards

B) XXXX Pharma limited:

- \* Research & Development & Formulation Unit
- \* Manufacture of the General category & solid oral dosage forms e.g. Tablets, capsules
- \* GMP Facility

C) XXXX India limited:

- \* Formulation Unit
- \* Manufacture of the solid oral dosage forms e.g. Tablets
- \* Facility approved by USFDA standards

D) XXXX Labs limited:

- \* Formulation Unit
- \* Manufacture of the Eye Drops / Injectables
- \* Facility approved by USFDA standards

E) Dr. XXXX Laboratories ltd:

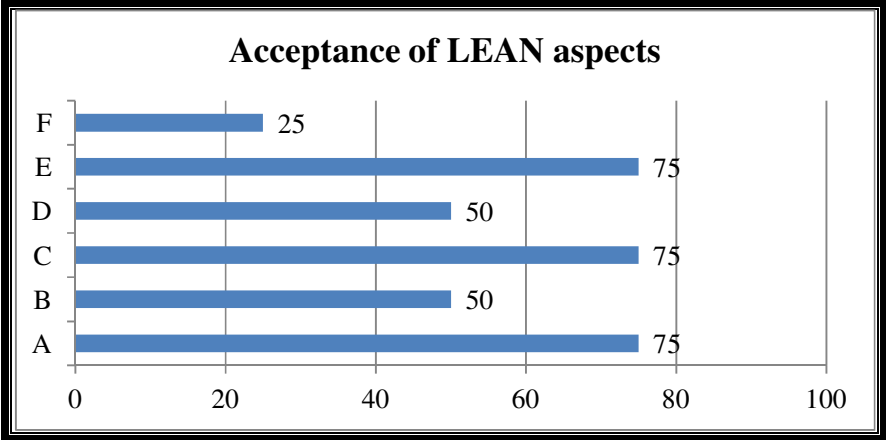
- \* Formulation Unit
- \* Manufacture of the Injections & R&D
- \* Facility approved by USFDA, MHRA standards

F) XXXX laboratories limited:

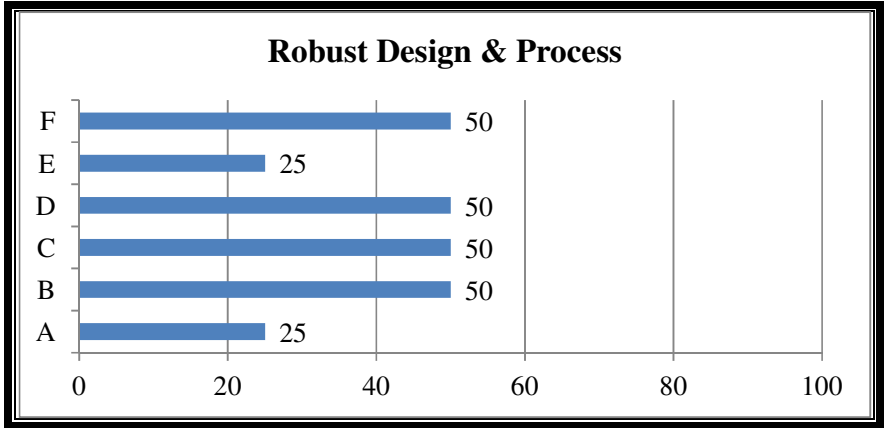
- \* Formulation Unit
- \* Manufacture of the solid oral dosage forms e.g. Tablets, Capsules
- \* Facility approved ISO 9001:2008 standards



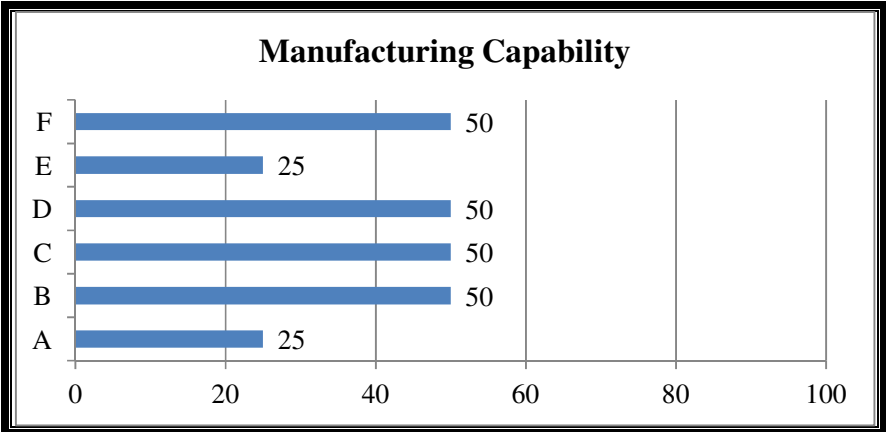
**DATA INTERPRETATION:  
SCOPE FOR IMPLEMENTATION OF LEAN PRINCIPLES IN PHARMA,**



**Figure 3:** Acceptance of LEAN Aspects



**Figure 4:** Robust Design & Process



**Figure 5:** Manufacturing Capability

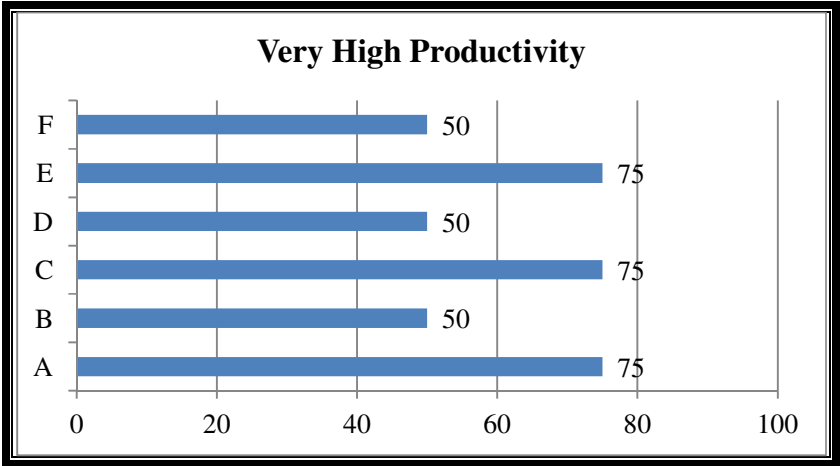


Figure 6: Very High Productivity

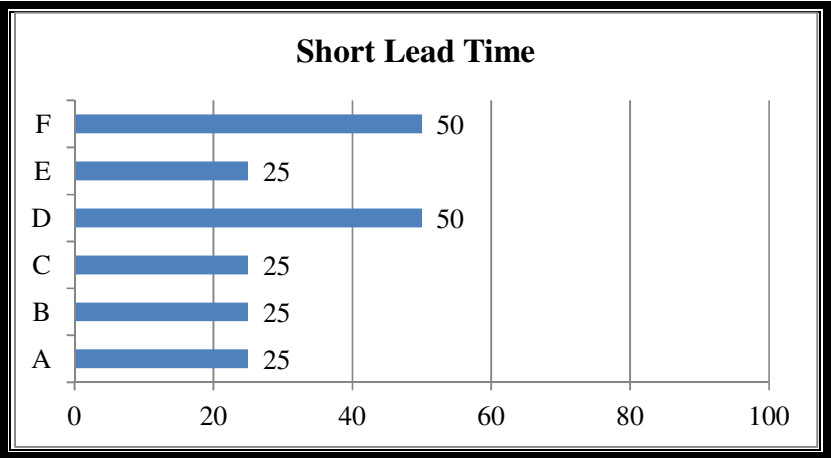


Figure 7: Short Lead time

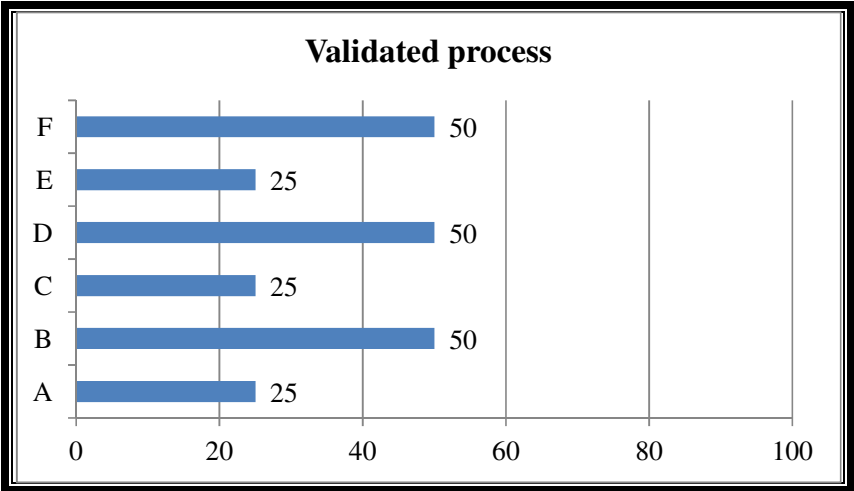


Figure 8: Validated Process

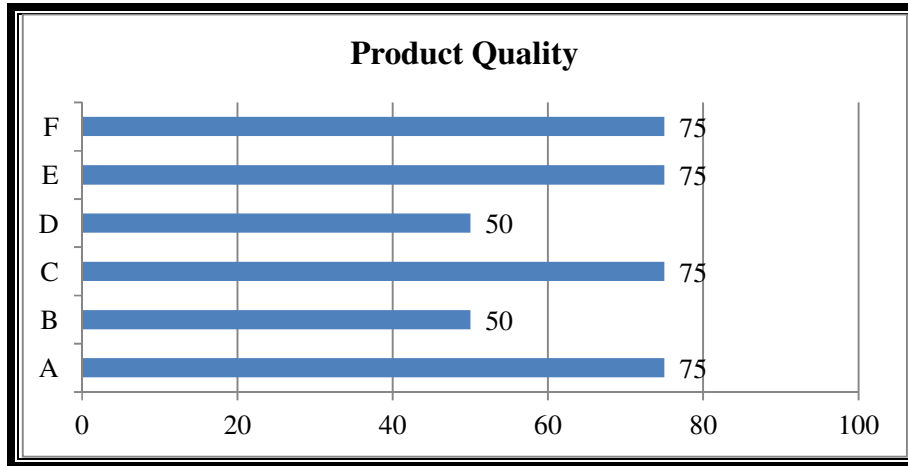


Figure 9: Product Quality

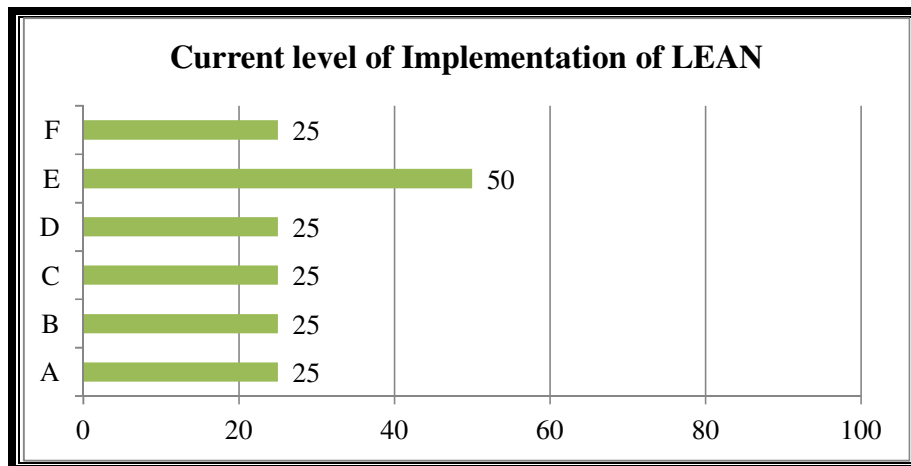


Figure 10: Current level of implementation LEAN

### 3.2 Results / Discussion from the Outcome of Research Survey:

From the above data represented in the graphs, it shows that many of the Pharmaceutical industries follow the cGMP prospective but there was lot of scope for the implementation of the LEAN management principles. Till today, the Pharmaceutical firms were mainly concentrating in the core aspect of ensuring the Product Quality through product development. Based on the initial survey / discussion, it was observed that there was lack of awareness about the lean principles in the various pharmaceutical industries. Most of the Pharma industries are concerned about the product quality with respect to cost and productivity.

INFERENCE FROM THE ABOVE SURVEY: LEAN implementation (around 25% only)

### IDENTIFICATION of the areas + IMPLEMENTATION OF LEAN = IMPROVED PRODUCT QUALITY

Effective quality management systems for the companies are the integral part of the company because it enables them to provide quality products. Based on the survey data analysis, it was observed that most of the companies are focus in ensuring the product manufacturing. Some of the companies are in robust design and validated process but existing process validation data helps them in improving product quality.

Core lean aspects like Robust design; validated process, Lead time like lean principles are not much implemented and improved. The main cause for the same is due to the lack of training and business process was not clearly defined.

The most important fact to be viewed in the survey was the lack of understanding and weak implementation of the lean practices implementation around 25% in the Pharmaceutical sectors.

Most of the pharmaceutical companies focus on the product quality thereby looking into the other aspects like reducing the cost, creating value etc. The management should realize that effective product quality will be achieved only through the effective quality management system through the implementation of the lean methods and Practices. In current scenario, many companies are following some process steps to achieve the best quality products. Based on the survey it was clearly understood that identified lean principles or methods to be implemented in cGMP environment with proper guidance to improve operational excellence to ensure that system will yield the desired results.

#### **4. CONCLUSION**

Change is inevitable and the only constant in today's world. Every Pharma industry has to implement the quality management systems in line with the management principles and sustain in the ever changing environment. Pharmaceutical field is no exception to this.

During the course of the study, it was found that there was a lot of scope for the implementation of the lean management principle in cGMP environment which was not clearly identified and implemented.

1. Based on the research study & data, it was clearly states that in the recent years more focus given to the product quality area. Moreover, some % of people was not aware completely about the scope of lean method and nature of the impact. But, if we look into the % business process for the awareness of the lean management it was found to be less and this would be the area for the scope of improvement.
2. Many of the people in the industry were not involved in the quality system implementation activity. Based on the management guidelines and training activities most of the lean principles to be implemented. Further, the higher management people are not completely transparent on their policies and procedures to implement the lean management principles in the cGMP environment.
3. Based on this research study, primary data review & research survey of the Pharma we have derived that employee knowledge on the lean management to be improved and senior level people should implement the lean management principles. A well-designed LEAN implementation enhances the reliability of product quality.

The following lean management principles derived from this research study are represented below which are to be implemented effectively in the Pharma environment to enhance the High productivity, short lead time with operational excellence and improve product quality.

- 1) Identify and Implement the LEAN aspects which Create value and reduce waste
- 2) Implement Lean methods effectively and slowly
- 3) Ensure robust design
- 4) Implement quality systems in line with LEAN
- 5) Validated process

### Outcome of the Research Study

A Continuous effort is essential to identify and implement the LEAN practices and principles in the Pharmaceutical sectors for the manufacturing of the pharmaceutical products to ensure that the product quality with high productivity in short lead time.

### 5. REFERENCES

1. John Drew, Blair McCollum, Stefan Roggenhoffer (2008) "Journey to Lean".
2. Juran, J. 1951 'Quality control hand book', New York, NY: McGraw-Hill.
3. Krisztina Demeter, Dávid Losonci, Zsolt Matyusz, István Jenei: The Impact of Lean Management on Business Level Performance and Competitiveness
4. Manimay Ghosh : Lean manufacturing performance in Indian manufacturing plants:
5. 4th International quality conference May 19th 2010, Article Title "Lean and Six sigma Concepts – application in pharmaceutical industry" Center for quality, Faculty of Mechanical Engineering, University of Kragujevac, Katarine Pavlovic.
6. Simpler.com Simpler Consulting Article Title – "Lean Management of the pharmaceutical sector brings increased efficiency and improved quality while increasing profits".
7. <http://www.item.unisg.ch/org/item/tectemw.nsf/SysWeb> "Operational Excellence in the Pharmaceutical Industry" Case studies from the field, Available from.
8. Craig Johnstone, Garry Pairaudeau, Jonas A. Pettersson: Creativity, innovation lean sigma: a controversial combination? Review Article Drug Discovery Today, Volume 16, Issues 1–2, January 2011, Pages 50-57.
9. Huw Thomas, Foster Wheeler Energy Limited, Foster FM Wheeler – "Transforming the Pharma Industry: lean thinking applied to Pharmaceutical manufacturing".
10. John Danese and Dennis Constantinou "Lean Practices in a life sciences organization"
11. "Innovation and continual Improvement in Pharmaceutical manufacturing" – [www.2004-4080b1\\_01\\_manufsciWP.pdf](http://www.2004-4080b1_01_manufsciWP.pdf).
12. Crosby, P. B. 1979 "Quality is free" New York, NY : McGraw-Hill .
13. Dahlgaard, J. J. and Dahlgaard-Park, S. M. 2006 " Lean production, six sigma quality" TQM and company culture .The TQM Magazine , 18 ( 3 ) : 263 – 281 [CrossRef]
14. Dahlgaard, J. J., Kristensen, K. and Kanji, G. K. 1998 "Fundamentals of total quality management "London: Chapman & Hill.
15. Dr. Isabella Erb – Herrman, Kaj Gricknik.. Booz & co "Beyond the blockbuster Lean manufacturing and Restructuring in Pharma".
16. ISO 9008:2000, "Guidance on the concept and use of the process approach for management systems" Oct 2008 Document ISO/TC 176/SC 2/N54R3.
17. U.S. Department of Health and Human Services, September 2004 "Guidance for industry: PAT A framework for innovative Pharmaceutical Development, Manufacturing and quality Assurance".
18. Ajay Verma, Dr. Anshul Gangele, "An Empirical Study Of The Investigation Of Green Supply Chain Management Practices In The Pharmaceutical Industry And Their Relation Drivers, Practices And Performances" International Journal of Mechanical Engineering & Technology (IJMET), Volume 3, Issue 3, 2012, pp. 654 - 668, ISSN Print: 0976 – 6340, ISSN Online: 0976 – 6359.